

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Offic**

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John

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/206,249 12/07/98 SEIBERG

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| EXAMINER |
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| MELLER, M | ART UNIT | PAPER NUMBER |
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1651

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DATE MAILED:

12/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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|------------------------------|--------------------------------------|---------------------------------------|
| Office Action Summary | Application No. 09/206,249 | Applicant(s) Selb rg et al. |
| | Examiner Michael Meller | Group Art Unit 1651 |

Responsive to communication(s) filed on Nov 10, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

Claim(s) 1-69 is/are pending in the application

Of the above, claim(s) 1, 3, 5-7, 23, 25-27, 37, 39, 41-43, 48-57, and 59-69 is/are withdrawn from consideration

Claim(s) _____ is/are allowed.

Claim(s) 2, 4, 8-22, 24, 28-36, 38, 40, 44-47, and 58 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 7

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

Art Unit: 1651

DETAILED ACTION

Information Disclosure Statement

Application serial number 09/110,409 has been considered as is evident from the following action. The citation of this application on a PTO-1449 is improper since the application has not yet been patented. If it is patented, then it would be appropriate to cite its patent number.

Election/Restriction

1. Applicant's election with traverse of Group II, claims 2, 4, 8-22, 24, 28-36, 38, 40, 44-47 and 58 and the election of species of soybean derivative (Andrea Colby elected on the phone 5/3/2000, the specific soybean derivative, soybean milk), keratinocytes and skin disorders as their elected species in Paper No. 5 is acknowledged. The traversal is on the ground(s) that searching all of the groups of the restriction requirement would not unduly burden the resources of the Patent Office. This is not found persuasive because as noted by the different classifications of the groups and due to the extensive literature search involved in searching the groups which is not co-extensive searching the other groups would in fact be a burden on the Patent Office.

Art Unit: 1651

Claims 1, 3, 5-7, 23, 25-27, 37, 39, 41-43, 48-57 and 59-69 remain withdrawn from further consideration by the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 2, 4, 8-21, 24, 28-35, 38, 40, and 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Limtrakul et al. (See abstract)

The elected species of the claims reads on soybean milk used to treat skin disorders.

The reference teaches that soybean milk can be used to treat a tumor on mouse skin.

Art Unit: 1651

4. Claims 2, 4, 8-22, 24, 28-36, 38, 40, 44-47 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Hagiwara et al. (See col. 1, line 50, col. 2, line 45-46, col. 4, line 46, and col. 5, line 36-37), Kosaka (see col. 2, line 5-6, lines 32-49), JP 62036304 (see abstract), JP 408143442A (see abstract), or JP 08143442A (see abstract).

The elected species of the claims reads on soybean milk used to treat skin disorders.

The references each teach using soybean milk to treat skin disorders.

5. Claims 2, 4, 8-22, 24, 28-36, 38, 40, 44-47 and 58 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 09/110,409 which discloses the composition of soybean milk and a cosmetically acceptable carrier/vehicle and discloses a method of using the composition which inherently will decrease phagocytosis or ICAM-1 expression in a mammalian cell as in the instant application.

Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future patenting of the copending application.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Art Unit: 1651

This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2, 4, 8-22, 24, 28-36, 38, 40, 44-47 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Limtrakul et al. (Limtrakul) taken with Kosaka, (see col. 2, line 5-6, lines 32-49), JP 62036304 (see abstract), JP 408143442A (see abstract), or JP 08143442A (see abstract).

The claims are drawn to the elected species composition (soybean milk and a pharmaceutical or cosmetically acceptable carrier) and method of using the composition to treat skin disorders.

Art Unit: 1651

Limtrakul teaches using soybean milk to treat a skin disorder, namely a tumor growing on the skin, see abstract.

The reference does not teach using the soybean milk on a human.

The secondary references each teach using soybean milk on human skin to treat a skin disorder.

Thus, it would have been obvious to one of ordinary skill in the art to treat a human with the composition of Limtrakul when Limtrakul was taken with the secondary references which teach that human skin can be treated with soybean milk to treat skin disorders.

Therefore, the claimed subject matter is *prima facie* obvious.

Double Patenting

8. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Art Unit: 1651

9. Claims 2, 4, and 8-22 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 60 of copending Application No. 09/110,409. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The above noted claims of the instant application and claim 60 of 09/110,409 are directed to the same composition (which reads on applicant's elected soybean milk) and a cosmetically acceptable vehicle/carrier.

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 2, 4, 8-22, 24, 28-36, 38, 40, 44-47 and 58 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-60 of copending Application No. 09/110,409. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Art Unit: 1651

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

The claims of the instant application are obvious over the claims of 09/110,409 since it is obvious to add a cosmetically acceptable carrier/vehicle to the claims of 09/110,409 as taught in the instant application. It is also obvious to use such a composition as claimed in 09/110,409 for the method of the instant application since adding a cosmetically acceptable carrier/vehicle is taught in the instant application and both applications teaching treating a patient with their respective compositions and the composition of 09/110,409 will inherently decrease phagocytosis or ICAM-1 expression in a mammalian cell as in the instant application.

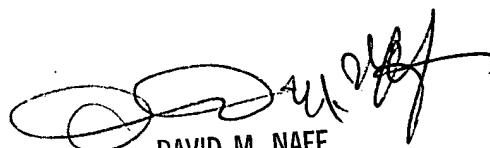
Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Any inquiries concerning this communication should be directed to Examiner Mike Meller at telephone number (703) 308-4230. If attempts to reach the examiner by telephone are

Art Unit: 1651

unsuccessful, the Examiner's supervisor, Michael Wityshyn, can be reached at (703) 308-4743.

The Fax phone number for the art unit is (703) 308- 0294. Any inquiries of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651